

**HEALTH AND SENIOR SERVICES
DIVISION OF HEALTH CARE SYSTEMS ANALYSIS**

Standards for Licensure of Children's Hospital Designation

Proposed Amendments: N.J.A.C. 8:43G-22A.2 and 22A.6

Authorized By: Mary W. Altamura, M.S., R.N., Chief of Staff, Department of Health and Senior Services (with approval of the Health Care Administration Board)

Authority: N.J.S.A. 26.2H-1 et seq. specifically 26:2H-5

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2003-55

Submit written comments by April 4, 2003 to:

John A. Calabria, Director
Certificate of Need and Acute Care Licensure Program
New Jersey Department of Health and Senior Services
P.O. Box 360, Room 403
Trenton, New Jersey 08625-0360

The Agency proposal follows:

Summary

The Department of Health and Senior Services (the Department) is proposing to amend N.J.A.C. 8:43G, Hospital Licensing Standards, in order to modify the minimum level of perinatal services required for designation as a children's hospital. The proposed amendments to N.J.A.C. 8:43G-22A change the minimum level of perinatal services required to be offered to a Community Perinatal Center – Intensive rather than a Regional Perinatal Center. Currently, the facilities designated as Children's Hospitals to which these proposed amendments shall apply include: Newark Beth Israel Medical Center, Cooper University Medical Center, Robert Wood Johnson University Hospital, St. Peter's Medical Center, St. Joseph's Hospital & Medical Center, Hackensack University Medical Center and Jersey City Medical Center. However, children's hospitals with previously existing designations as a Regional Perinatal Center shall not be affected by the proposed amendments.

The proposed amendments are designed to ensure that facilities licensed as children's hospitals provide essential special care services appropriate for higher acuity neonates and pediatric patients, while taking cognizance of current unresolved issues concerning policy governing the organization and delivery of perinatal and pediatric services in New Jersey, as well as the role of the Maternal and Child Health Consortia in the certificate of need process for these services.

Public Law 1997, chapter 48 eliminated certificate of need (CN) requirements for many types of health care services and facilities. It also called for a CN Study Commission to determine the impact that the elimination of CN requirements would have on all health care services or facilities remaining subject to the CN process. The Commission issued its report in February of 2000, recommending that, among other types of services and facilities, children's hospitals, neonatal intermediate and intensive services, specialized perinatal services, pediatric intensive care services, and maternal and child health consortia all remain subject to certificate of need requirements. At the same time, the Commission called for a study of the consortia's funding and effectiveness. The Department subsequently commissioned a report by the Rutgers Center for State Health policy that looked at the issue of the effectiveness and perceived value of the services provided by the consortia. While this study was being prepared and reviewed, in order to avoid an expiration of rules, the Department readopted without amendment, on March 4, 2002, N.J.A.C. 8:33C, Certificate of Need and Licensure Rules for Regionalized Perinatal Services and Maternal and Child Health Consortia. At the time of the readoption proposal, the Department indicated that a study of the maternal and child health consortia was ongoing and not expected to be completed before the 2002 expiration date. The Department also stated it was proposing the rules for readoption without amendment, pending a full review of the study's findings. The study concluded that, while the consortia are generally perceived by their members to provide valuable services, there is also interest in the consortia's increasing their responsiveness to their members and effectiveness.

The Department, together with the existing consortia, has now initiated a process to reexamine not only the structure and funding of the consortia, but also the organization and need methodologies across the entire range of perinatal and intensive pediatric services. In light of recent concerns focusing specifically on the role of regional perinatal centers in the continuum of pediatric specialized services, it is appropriate, pending the completion of the consortia's review process, to take a more limited approach to the essential services required for a children's hospital.

Briefly summarized, the Department's amendments are as follows:

N.J.A.C. 8:43G-22A.6(c) is amended to substitute the word "any" for "either," to reflect the fact that three alternatives follow, not two.

N.J.A.C. 8:43G-22A.6(c) is amended to require that within one year of the effective date of the newly promulgated children's hospital rules (that is, October 31, 2003, see 34 N.J.R. 3637(b)), children's hospitals are to be required to operate a "community perinatal center – intensive" (CPC – Intensive) rather than a regional perinatal center (RPC). The amendments also replace the regulatory requirements for an RPC with those for a CPC-Intensive service.

N.J.A.C. 8:43G-22A.6(d) is amended to state that, as of the effective date of the children's hospital licensure rules, October 31, 2002, a children's hospital not as yet licensed as a CPC – Intensive rather than a RPC is permitted to file a licensing application to establish such a program, including both intermediate and intensive neonatal units in accordance with N.J.A.C. 8:43G-2.2 through 2.5.

N.J.A.C. 8:43G-22A.6(e) is amended to state that a children's hospital not licensed to operate a pediatric intensive care unit or a CPC-Intensive shall not be required to obtain a certificate of need approval for the establishment of such units.

As the Department has provided for a 60-day comment period for this notice of proposal, this notice is excepted from the rulemaking calendar requirements, pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

The licensing standards for designated children's hospitals establish the minimum standards of practice for providing highly specialized pediatric services. These proposed amendments will continue to enable children's hospitals to provide the greater intensity of services designed specifically for the unique needs of children who require hospital care; for example, the availability of neonatal intensive care bassinets for extremely low birth weight infants is facilitated at all designated children's hospitals by these amendments through the Department's rigorous licensure process.

Economic Impact

The proposed amendments to N.J.A.C. 8:43G-22A.6(c) through (e) are not anticipated to impose any additional economic burden on licensed children's hospitals and may actually reduce costs to the extent that fewer services are required to be offered by a CPC-Intensive compared to an RPC. The proposed amendment to N.J.A.C. 8:43G-22A.2 is a grammatical correction and imposes no economic impact.

Job Impact

The Department does not anticipate that any jobs will be generated or lost as a result of the proposed amendments.

Federal Standards Statement

Federal standards governing acute care hospitals are contained within Chapter IV: Health Care Financing Authority; Subchapter E: Standards and Certification; 42 C.F.R. Part 482, Conditions of Participation for Hospital in relation to New Jersey licensing standards for hospitals. Those Federal Conditions of Participation are used as a survey mechanism for selected hospitals participating as providers in the Medicare and Medicaid Programs. In general, the Conditions of Participation are not comprehensive and have not been updated since 1991. Accordingly, many of the rules contained in N.J.A.C. 8:43G intentionally exceed Federal standards. The amendments proposed herein do not exceed those standards.

Agriculture Industry Impact

The proposed amendments will have no impact on the agriculture industry in New Jersey.

Regulatory Flexibility Statement

The proposed amendments will not affect small businesses as they are defined in the Regulatory Flexibility Act, N.J.S.A. 54:14B-16 et seq. New Jersey hospitals, all of which are governed by N.J.A.C. 8:43G, all employ well over 100 people full-time and, thus, are not defined as small businesses under the Act. Accordingly, no regulatory flexibility analysis is required.

Smart Growth Statement

The proposed amendments shall not have an impact on the achievement of smart growth and the implementation of the State Development and Redevelopment Plan.

Full text of the proposal follows (additions indicated in boldface **thus**, deletions indicated in brackets [thus]):

8:43G-22A.2 Organizational structure

(a)-(b) (No change.)

(c) The children's program shall have fiscal autonomy which shall conform with [either] **any** of the following:

1.-3. (No change.)

8:43G-22A.6 Essential special care services

(a)-(b) (No change.)

(c) By October 21, 2002, all licensed children's hospitals shall operate a [regional perinatal center] **community perinatal center – intensive** in accordance with N.J.A.C. 8:43G-19, and applicable provisions of N.J.A.C. 8:33C, including 8:33C-3.4[(a)3 through 10] **(b)1 through 4**.

(d) A licensed children's hospital not licensed to operate a [regional perinatal center] **community perinatal center – intensive** on October 21, 2002 shall file a licensing application to initiate such a service, including neonatal intermediate and intensive care unit(s), in conformance with (c) above. Such a licensing application shall be filed in accordance with the procedures described in N.J.A.C. 8:43G-2.2 through 2.5, as applicable.

(e) A licensed children's hospital not also licensed to operate a pediatric intensive care unit or a [regional perinatal center] **community perinatal center – intensive** on October 21, 2002 shall not be required to obtain certificate of need approval to establish such a unit or center, including neonatal intensive or intermediate care unit(s) within the center.

1.-2. (No change.)